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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
12/15/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/529,014	AKIMOTO ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-35* is/are pending in the application.

4a) Of the above claim(s) *20-31 and 33-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-19 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :6/30/10, 7/21/10, 8/11/10, 10/20/10,12/2/10

DETAILED ACTION

1. Applicants' arguments, filed October 13, 2010, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1 – 6, 8 – 12 and 32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 20, 28 - 31 and 34 – 36 of copending Application No. 10/485456. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed April 13, 2010 and those set forth below.

Applicant asks that this rejection be held in abeyance until it is the only remaining rejection. Therefore this rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 112 – 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1 – 6, 8 – 19 and 32 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This new matter rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed April 13, 2010 and those set forth below.

Applicants argue that the disclosure of the specific ranges does not render the broader range unsupported where that range is explicitly disclosed. These arguments are unpersuasive. The disclosure of daily intakes of 0.20 g (200 mg) of arachidonic acid (AA) and the ingestion of a corresponding amount or greater does not relate to the claimed method and dosages of arachidonic acid which were contemplated for use in the method. There was no nexus in the application as originally filed linked between the claimed dosage range of 0.2 g or greater of AA and the claimed method. "Thus, the daily intake of arachidonic acid or a compound with arachidonic acid as a constituent fatty acid *according to the invention* for an adult ... is 0.001 - 20 g, preferably 0.01 – 10 g, more preferably 0.05-5 g and most preferably 0.1-2 g, in terms of arachidonic acid" (p 19, ln 14 – 20 of the instant specification, emphasis added). The dosage ranges linked to the invention overlap with the recited range but none have an end point of 0.2 g or dosages of above 20 g. The range of the instant claims encompasses dosages of more than 20 g.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 13 – 19 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Kelley et al. (Lipids 1998). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed April 13, 2010 and those set forth below.

Applicant traverses this rejection on the grounds that Kelley does not disclose the limitation of "the composition contains no eicosapentaenoic acid or an amount not exceeding 1/5 of the arachidonic acid in the composition" [a limitation previously recited in claim 32]. Kelley fails to disclose the concentration of eicosapentaenoic acid (EPA) and arachidonic acid in the oil added. These arguments are unpersuasive. The basal diet of Kelley provides 200 mg AA (arachidonic acid) per day (p 126, col 1, ¶ 2) and the supplemented diet contains 1.5 g/day (p 126, col 1, ¶ 1). As the diet of Kelley is natural foods and is adequate in all nutrients (p 126, col 1, ¶ 2) and EPA can be obtained from dietary sources including cold water fatty fish, the basal diet contains some EPA. The ARASCO® oil does not contain any detectable amounts of EPA (see DHASCO® and ARASCO® information sheet accompanying this action, section 3). While this information sheet also indicates the AA concentration in ARASCO®, the relevant information is the total AA per day, which Kelley clearly states to be 200 mg/day in the

basal (low AA) diet and 1.5 g/day in the supplemented diet. Given the large addition of AA to the basal diet using a source of AA with no detectable EPA, there is no reason to believe that the basal diet administered by Kelley contains more than 0.3 g (1/5 of 1.5 g) of EPA. It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Applicants also argue that Kelley fails to disclose administering the composition to "prevent decline, improve, or enhance cognitive ability responds of the health person" as Kelley measures the immune system response and section of prostaglandins E2 and leukotriene B4, none of which relate to prevention of decline improvement or enhancement of cognitive ability responses. These arguments are unpersuasive. As set forth previously (see p 6 of April 13, 2010 Office Action), the active step of the instant claims is the administration of a composition containing at least 200 mg (0.2 g) of AA to a healthy adult person. Kelley et al. teaches administration of a basal diet (a composition) containing 0.2 g AA/day or a supplemented diet with 1.5 g AA/day to healthy adult persons. The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977) (MPEP 2112). As the same active step with the same patient population is taught by the cited

art as is required in the instant claims, the same outcome must inherently occur. The failure of Kelley to test cognitive abilities does not mean that the effects required by Applicant did not occur as the same result must occur when the same step is carried out with the same patient population.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 2, 8, 9, 13 – 19 and 32 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kelley et al. (Lipids 1998) in view of Barclay (US 5,583,019). This

rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed April 13, 2010 and those set forth below.

Applicants present no separate arguments in regards to the Barclay reference so this and the rejection below (further in view of JP 08-214891) have been discussed together below.

11. Claims 1 – 6, 8 – 19 and 32 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kelley et al in view of Barclay further in view of JP 08-214891 (JP'481). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed April 13, 2010 and those set forth below.

Applicants argue that the'891 application discloses compositions with EPA concentrations that are higher than the AA concentration (see, e.g., tables 1 – 3). Therefore there would be no expectation of success in combining the disclosures of Kelley, Barclay and JP'891. These arguments are unpersuasive. The examples of '891 relate to the making of triglycerides using tuna oil fatty acids, which contains both AA and EPA. JP'891 does not require the use of a fatty acid mixture containing more EPA than AA. It appears that the data in the tables [machine translations do not translate tables and applicants do not provide a translation of the Japanese text in the tables] relate to the final fatty acid content of the samples that were from a tuna oil fatty acid mixture. JP'891 discloses that fatty acids like AA alone or extracted from natural sources (e.g., tuna (fish) oil) can be used as the constituent fatty acids with medium

chain fatty acids at position 1 and 3 of the triglyceride with a higher unsaturated fatty acid (AA or DHA) at the 2 position (¶ [0011]). When a purified AA oil for use in infant formulation that contains little or no EPA as disclosed by Barclay (col 1, ln 37 - 40) is used in the method of JP'891, triglycerides with little to no EPA will be produced, allowing for higher concentration of the higher unsaturated fatty acids (e.g., AA) to be achieved and/or higher concentrations of the higher unsaturated fatty acids by adding of less of the fatty acid containing ingredient. A reasonable expectation of success is present because all of the references relate to long chain, polyunsaturated fatty acids (PUFAs) such as AA and the use of these PUFAs to prepare and administer such compositions.

Lastly, Applicants again argue that Kelley fails to disclose administering the composition to "prevent decline, improve, or enhance cognitive ability responds of the health person" as Kelley measures the immune system response and section of prostaglandins E2 and leukotriene B4, none of which relate to prevention of decline improvement or enhancement of cognitive ability responses. These arguments are unpersuasive. As set forth previously (see p 6 of April 13, 2010 Office Action), the active step of the instant claims is the administration of a composition containing at least 200 mg (0.2 g) of AA to a healthy adult person. Kelley et al. teaches administration of a basal diet (a composition) containing 0.2 g AA/day or a supplemented diet with 1.5 g AA/day to healthy adult persons. The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977) (MPEP

2112). As the same active step with the same patient population is taught by the cited art as is required in the instant claims, the same outcome must necessarily occur. The failure of Kelley to test cognitive abilities does not mean that the effects required by Applicant did not occur as the same result must occur when the same step is carried out with the same patient population.

Claim 32 which requires the presence of EPA in an amount not more than 1/5 the amount of AA. As disclosed by Barclay, large amounts of EPA or other long chain highly unsaturated fatty acids can hinder further processing to achieve appropriate ratios of fatty acids (col 1 ln 37 - 46) but complete removal of EPA, particularly from naturally derived sources, may not be practical and/or economically feasible. The use of an AA source to supplement the basal diet in Kelley from which not all of the EPA has been removed will result in AA supplemented compositions that contain trace amounts of EPA, meeting the limitation of claim 32.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nissa M Westerberg/
Examiner, Art Unit 1618